

Remarks

Claim 1 is amended herein to correct typographical errors. Claims 46-48 are canceled herein, without prejudice. Following entry of this amendment, claims 25-45 are pending. No new matter is added herein. Examination of the subject application is respectfully requested.

Restriction Requirement

In response to the restriction requirement, Applicants elect with traverse Group I (claims 25-27 and 45), drawn to a vaccine composition comprising antigenic material that is a live mutant bacterium having a genome wherein the *fur* gene has been modified by mutation so that expression of its gene product is regulated independently of iron concentration, and a non-viable preparation including antigens from cultured cells of this bacterium.

Applicants submit that it would not be an undue burden for the Examiner to search the subject matter of Group I (drawn to a live bacterium and membrane preparations from this bacterium) with the subject matter of Group II (drawn to an attenuated bacterium having a genome wherein the *fur* gene has been modified by mutation so that expression of its gene product is regulated independently of iron concentration). In both types of bacteria, the same gene is mutated (the *fur* gene) and the same effect of expression is demonstrated (expression of its gene product is regulated independently of iron concentration). Thus, it would not be an undue burden on the Examiner to examine the subject matter of Group I (claims 25-27 and 45) with the subject matter of Group II (claims 28-41) drawn to an attenuated bacterium.

Applicants submit that the special technical feature of the invention as claimed in Groups I and II is a bacterium having a genome wherein the *fur* gene has been modified by mutation so that expression of its gene product is regulated independently of iron concentration. The subject

matter of Group I is a live bacterium and preparations made from this live bacterium. The subject matter of Group II is also a live bacterium. The on-line medical dictionary (<http://cancerweb.ncl.ac.uk/cgi-bin/omd?attenuated>) defines attenuated as “Attenuated: To reduce the virulence (infectivity) of a pathogenic microorganism.” The dictionary of cancer terms (http://www.cancer.gov/dictionary/db_alpha.aspx?expand=A#attenuated) further discusses attenuated organisms. This dictionary states “Attenuated strains of disease-causing bacteria and viruses are often used as vaccines...they stimulate a protective immune response while causing no disease or only mild disease in the person receiving the vaccine.”

Thus, Applicants submit that there is a special technical feature (both groups are drawn to a bacterium having a genome wherein the *fur* gene has been modified of mutation so that expression of its gene product is regulated independently of iron concentration). Thus, it would not be an undue burden on the Examiner to search the subject matter of Group I with Group II. If the subject matter of these two groups is rejoined, Applicants elect the following species:

- (1) A mutation in the *aro* genes, such as *aroB*

Applicants note that upon the allowance of a generic claim, the Applicant is entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim.

Applicants further note that Group III (claims 42-43) is drawn to an attenuated mutant *N. meningitidis* strain. Attenuated *N. meningitidis* is one species of an attenuated bacterium (the subject matter of Group II). Moreover, these attenuated mutant *N. meningitidis* strains include alterations in the *fur* gene under the control of the *lac* promoter (see the specification at page 16, lines 8-18). Thus, these *N. meningitidis* bacteria are bacteria having a genome wherein the *fur* gene has been modified by mutation so that expression of its gene product is regulated

independently of iron concentration. Applicants submit that the subject matter of Groups II and III should be rejoined as it would not be an undue burden on the Examiner to search the subject matter of Group II with Group III. If the subject matter of these two groups is rejoined, Applicants elect the following species:

42(a) mutation of aroB, lac:fur fusion, and mutation of recA;

Applicants note that upon the allowance of a generic claim, the Applicant is entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim.

Reconsideration and rejoining of the subject matter of Groups I-III is respectfully requested.


Conclusion

If there are any matters to be addressed before substantive examination of the claims, the Examiner is respectfully requested to contact the undersigned using the telephone number shown below.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

By



Susan Alpert Siegel, Ph.D.
Registration No. 43,121

One World Trade Center, Suite 1600
121 S.W. Salmon Street
Portland, Oregon 97204
Telephone: (503) 226-7391
Facsimile: (503) 228-9446